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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/511,096

10/14/2004

Heinz Von der Kammer

P67813US1

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7590

07/21/2006

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EXAMINER

BALLARD, KIMBERLY A

ART UNIT

PAPER NUMBER

1649

DATE MAILED: 07/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/511,096	Applicant(s) VON DER KAMMER ET AL.	
	Examiner Kimberly A. Ballard	Art Unit 1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 November 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-20 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-8, as specifically drawn to the special technical feature method of diagnosing, monitoring progression of, or evaluating treatment for a neurodegenerative disease in a subject, and kit comprising same, comprising determining a level and/or activity of a transcription product or fragment thereof of a gene coding for golgin-245.

Group II, claim(s) 1-8, as specifically drawn to the special technical feature method of diagnosing, monitoring progression of, or evaluating treatment for a neurodegenerative disease in a subject, and kit comprising same, comprising determining a level and/or activity of a translation product, or fragment thereof, of a gene coding for golgin-245.

Group III, claim(s) 9, as specifically drawn to the special technical feature method of treating or preventing a neurodegenerative disease in a subject comprising administering an agent which directly or indirectly affects an activity and/or a level of a gene coding for golgin-245, or a fragment thereof, or a transcription product of golgin-245.

Group IV, claim(s) 9, as specifically drawn to the special technical feature method of treating or preventing a neurodegenerative disease in a subject comprising administering an agent which directly or indirectly affects an activity and/or a level of a translation product, or a fragment thereof, of a gene coding for golgin-245.

Group V, claim(s) 10, as specifically drawn to the special technical feature modulator of an activity and/or a level of a gene coding for golgin-245 or a transcription product or fragment thereof.

Group VI, claim(s) 10, as specifically drawn to the special technical feature modulator of an activity and/or a level of a translation product, or fragment thereof, of a gene coding for golgin-245.

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Group VII, claim(s) 11, drawn to the special technical feature recombinant non-human animal comprising a non-native gene sequence coding for golgin-245.

Group VIII, claim(s) 12-15, as specifically drawn to the special technical feature method of screening for a modulator of a gene coding for golgin-245 or a transcription product or fragment thereof, comprising administering a test compound to a test animal model of neurodegenerative disease.

Group IX, claim(s) 12-15, as specifically drawn to the special technical feature method of screening for a modulator of a translation product, or fragment thereof, of a gene coding for golgin-245, comprising administering a test compound to a test animal model of neurodegenerative disease.

Group X, claim(s) 16-17, drawn to the special technical feature assay method for testing an inhibitory or binding compound of golgin-245 *in vitro*.

Group XI, claim(s) 18-19, drawn to the special technical feature golgin-245 protein molecule.

Group XII, claim(s) 20, drawn to the special technical feature use of an antibody specifically immunoreactive with a translation product of golgin-245 (interpreted as a product).

The inventions listed as Groups I-XII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The technical feature linking groups I-XII appears to be that they all relate to gene products derived from the gene coding for golgin-245. However, Fritzler MJ et al. (*J Biol Chem*, 1995; **270**(52): 31262-31268; listed on Applicant's IDS filed 04/01/2005) teaches the molecular characterization of, including both the nucleotide and deduced amino acid sequences of the cDNA clone encoding for golgin-245 (see Figure 3). Accordingly, the technical feature linking the inventions of groups I-XII does not constitute a special technical feature as defined by PCT Rule 13.2, as it does not define a contribution over the prior art.

Additionally, the PCT rules provide for the examination of the first claimed product, the first claimed method of making that product, and the first claimed method of using that product in one application, but do not provide for the examination of multiple products or unrelated methods. For example, the modulators, recombinant animal, protein and antibody differ in structure, biological function, and capable uses. The methods use different steps and different reagents corresponding to the distinct technical features, and exhibit different effects, functions and outcomes.

The special technical feature of Group I is considered to be a method and kit of diagnosing, monitoring the progression of, or evaluating treatment for a neurodegenerative disease in a subject comprising determining a transcription product of golgin-245. The method and kit of Group I is not required for the diagnostic method of group II, the treatment methods of Groups III-IV, the modulators of Groups V-VI, the recombinant non-human animal of Group VII, the methods of screening of Groups VIII-IX, the *in vitro* assay method of Group X, the protein of Group XI, or the antibody of Group XII.

The special technical feature of Group II is considered to be a method and kit of diagnosing, monitoring the progression of, or evaluating treatment for a neurodegenerative disease in a subject comprising determining a translation product of golgin-245, which is not required by Groups I or III-XII.

The special technical feature of Group III is considered to be a method of treating or preventing a neurodegenerative disease in a subject comprising administering an agent which affects a transcription product of golgin-245, which is not required by Groups I-II or IV-XII.

The special technical feature of Group IV is considered to be a method of treating or preventing a neurodegenerative disease in a subject comprising administering an agent which affects a translation product of golgin-245, which is not required by Groups I-III or V-XII.

The special technical feature of Group V is considered to be an agent that modulates the activity and/or level of a golgin-245 gene, transcription gene product, or fragments or derivatives thereof, which is not required by Groups I-IV or VI-XII.

The special technical feature of Group VI is considered to be an agent that modulates the activity and/or level of a translation product of golgin-245, or fragments or derivatives thereof, which is not required by Groups I-V or VII-XII.

The special technical feature of Group VII is considered to be a recombinant, non-human animal comprising a non-native gene sequence coding for golgin-245, which is not required by Groups I-VI or VIII-XII.

The special technical feature of Group VIII is considered to be a method of screening for a modulator of a golgin-245 gene or a transcription gene product or fragment thereof, comprising administering a test compound to a test animal, which is not required by Groups I-VII or IX-XII.

The special technical feature of Group IX is considered to be a method of screening for a modulator of a translation product of golgin-245, comprising administering a test compound to a test animal, which is not required by Groups I-VIII or X-XII.

The special technical feature of Group X is considered to be an assay method for testing a compound *in vitro*, which is not required by Groups I-IX or XI-XII.

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The special technical feature of Group XI is considered to be a protein that is a translation product of the golgin-245 gene, which is not required by Groups I-X or XII.

The special technical feature of Group XII is considered to be an antibody that specifically binds to a translation production of a gene coding for golgin-245, which is not required by Groups I-XI.

Accordingly, Groups I-XII are not so linked by the same or a corresponding special technical feature as to form a single general inventive concept.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kimberly A. Ballard whose telephone number is 571-272-4479. The examiner can normally be reached on M-F 9am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached on 571-272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Kimberly Ballard, Ph.D.
Art Unit 1649
July 10, 2006



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